

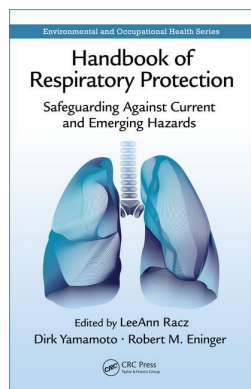
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Publisher: *CRC Press*

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Handbook of Respiratory Protection Safeguarding against Current and Emerging Hazards

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Facemasks and Respirators for the Prevention of Infection in Healthcare and Community Settings

Publication details

<https://www.routledgehandbooks.com/doi/10.4324/9781351109079-16>

C. Raina MacIntyre, Abrar Ahmad Chughtai

Published online on: 29 Nov 2017

How to cite :- C. Raina MacIntyre, Abrar Ahmad Chughtai. 29 Nov 2017, *Facemasks and Respirators for the Prevention of Infection in Healthcare and Community Settings from: Handbook of Respiratory Protection, Safeguarding against Current and Emerging Hazards* CRC Press

Accessed on: 09 Apr 2021

<https://www.routledgehandbooks.com/doi/10.4324/9781351109079-16>

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16

Facemasks and Respirators for the Prevention of Infection in Healthcare and Community Settings

C. Raina MacIntyre and Abrar Ahmad Chughtai

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16.1 Introduction

16.1.1 Infection Control and Personal Protective Equipment

Emerging and reemerging infectious diseases are a continuing threat globally. Various pharmaceutical and non-pharmaceutical infection control measures are employed in healthcare and community settings to control infectious diseases. Most research has focused on pharmaceutical measures such as drugs and vaccines, but personal protective equipment (PPE) and other non-pharmaceutical measures are often the first available protection for frontline responders. These infection control measures are generally categorized according to three levels of hierarchy: administrative control measures, environmental control measures, and use of PPE (Siegel et al. 2007,

WHO 2014a). Administrative control measures include elimination of risk, substitution, and engineering controls. These controls require development of policies and procedures, assigning responsibilities, risk assessment, source control, education, and training. Environmental control includes measures aimed at reducing the spread of infections through room design, isolation and air exchange measures such as proper ventilation, establishing airborne infection isolation rooms and systems for cleaning and waste disposal. PPE includes clothing or equipment used to protect from biological, chemical, and other hazardous substances such as gloves, gowns, aprons, goggles, face shields, surgical caps, facemasks, and respirators. PPE is considered the last line of defense in the infection control hierarchy and is recommended in combination with other control measures. However, in the event of an outbreak or a pandemic, the nature of the pathogen may be unknown and drugs and vaccines may not be available in the early phase, making PPE critical (Bell et al. 2006).

PPE should also be seen from two perspectives: as an infection control strategy to protect patients and as an occupational health and safety strategy to protect the health of healthcare workers (HCWs). PPE guidelines and protocols in healthcare, however, have developed largely around infection control and have focused on patient safety, with less attention to healthcare worker safety (MacIntyre et al. 2014a,b,c). PPE is required for first responders (including paramedics, border control staff, and emergency services), hospital workers, as well as staff in primary care, public health, or involved in biological waste disposal.

The choice of infection control measures generally depends on the nature of the infectious agent, routes of transmission, severity of disease, number of cases (sporadic, outbreak, or pandemics), geographical spread, and availability of prevention and control measures (MacIntyre et al. 2014c). The precautionary principle is recommended when there is uncertainty about any of these parameters, and especially if the consequences of infection are severe (MacIntyre et al. 2014a,b,c). A multi-faceted approach using a combination of the various infection control strategies is generally recommended to decrease the transmission of infectious diseases. Infection control strategies also need to be tailored for the setting and would be different in a high-risk setting, such as intensive care, compared to a general ward or community clinic in healthcare and community settings. HCWs are on the front-line when it comes to dealing with infectious disease and are at increased occupational risk of contracting infections compared to the general public. Common infection control strategies used in healthcare settings are triage, isolation of infective cases, negative pressure rooms, cohorting, use of drugs, vaccines, and PPE. During large outbreaks and pandemics, the focus may shift to mitigation, delaying spread, and reducing community transmission through population-based measures. Common interventions used to reduce the spread of epidemics in the community are quarantine, social distancing, and use of PPE (Bell et al. 2006).

16.1.2 Types of PPE

Various types of PPE are used in healthcare and community settings to protect from respiratory and other infections. PPE can be categorized into:

- Respiratory protection (facemasks and respirators)
- Skin protection (full body suit or gown/apron, surgical hood/cap, gloves and shoes/shoe cover)
- Eye protection (goggles or face shield)

16.1.2.1 Respiratory Protection

As respiratory infections are mostly transmitted through the inhalation route, appropriate respiratory protection is required (IOM 2006, OSHA 2014). Based on aerobiology experiments from the 1940s which suggested that large respiratory droplets settle quickly close to the source of emission, and small droplets remain airborne at a greater distance (Wells 1943, 1946, Wells et al. 1948, Brosseau and Jones 2014), respiratory transmission of infection is usually dichotomized into droplet or airborne, and infection control policies are formulated around this dichotomy. Yet scientific research shows that the scientific basis of this assumption is incorrect, and that both small and large droplets can be present close to the source. Infection transmission is more complex than simply being airborne or droplet. Facemasks (also known as “surgical” or “medical” masks) and respirators are the most common PPE used to protect from respiratory transmission. Facemasks are mostly used to avoid contact with splashes and sprays of body fluids or blood and to prevent the spread of infections from sick patients (Siegel et al. 2007). They are not designed for respiratory protection and are not classified as respiratory protective devices (IOM 2010). Respirators (which may be disposable or reusable) are designed for respiratory protection and are widely accepted in healthcare settings to protect HCWs from acquiring respiratory infections (MacIntyre et al. 2011, 2013, WHO 2014a). Respirator use requires implementation of comprehensive respiratory protection programs, including regulation, certification, training, fit testing, medical evaluation, surveillance, storage, inspection, and decontamination.

16.1.2.2 Skin Protection

Gloves are used to protect the hands from infections which transmit through direct contact. The transmission may occur directly through non-intact skin or contamination through touching of the hand to a mucosal surface. Hand washing is strongly recommended before and after use of gloves. Hands can be washed with soap and water, antiseptic solutions, and antibacterial microfiber towel. Alcohol-based hand rubs (ABHRs) may not be effective in reducing *Bacillus atrophaeus* (a surrogate of *Bacillus anthracis*) spores, and proper

hand wash is recommended using soap and water and other antiseptic liquids (Weber et al. 2003). For some infections, such as Ebola, double gloving is also recommended to increase the safety of removal (McLaws et al. 2016).

Disposable or washable gowns are used to avoid soiling of the clothes with blood and body secretions. Gowns prevent contamination of clothes which may otherwise lead to transferring microorganisms from one area to another. Disposable or washable gowns are used to avoid soiling of clothes with blood and body secretions. Gowns are not recommended as a measure to prevent respiratory pathogen transmission (such as influenza) in general, except during certain procedures such as intubation and resuscitation (US Department of Health and Human Services 2005). However, gowns are recommended if the outbreak is also associated with bleeding or diarrhea (US Department of Health and Human Services 2005) and in the case where a new emerging infection is suspected, for example, severe acute respiratory syndrome (SARS) (WHO 2014b).

16.1.2.3 Eye Protection

Goggles or face shields are used to protect the transmission of biological agents directly into the eyes or self-contamination from contaminated hands. Studies show that trans-ocular transmission of influenza and other viruses may occur, and transmission may be reduced further if eye protection is used with respiratory protection (Bischoff et al. 2011). Conjunctivitis associated with H7N7 avian influenza infection reported in the Netherlands also suggests that transmission may occur through the conjunctiva (Du Ry van Beest Holle et al. 2005). However, goggles or face shields are not routinely used for all diseases that transmit through direct contact. In healthcare settings, they are mainly recommended to avoid sprays or splashes of infective material (US Department of Health and Human Services 2005) and also while dealing with serious pathogens. For example eye protection was strongly recommended for the prevention of transmission of SARS (WHO 2014b) and Ebola (McLaws et al. 2016).

16.2 Facemasks and Respirators

Protection from masks is a function of four theoretical factors:

1. Physical barrier: this simply blocks skin contact with splashes or sprays, and depends on the surface area and permeability of the material.
2. Filtration: this is a function of the fabric or material chosen, and its ability to filter airborne particles.

3. Fit around the face: this is a function of the design of the mask, and the ability to prevent air leaking through the sides of the mask.
4. Antimicrobial properties of the material. However, commercial products with the feature are not widely available.

The use of facemasks by surgeons in operation theaters (OTs) to protect the wound from contamination was first documented in the late nineteenth century (Belkin 1997, Weaver 1919). In the early twentieth century, cloth masks were used to protect from diphtheria, scarlet fever, and other respiratory infections (Capps 1918, Weaver 1918, 1919). HCWs and the general public also used cloth masks during the Spanish influenza pandemic (1918) (NSWDPH 2007), Brooks 1918, Whitelaw 1919, Kellogg and MacMillan 1920), Manchurian epidemic (1920–1921) (Wu 1926), and plague epidemic (1924) (Visel tear 1974). Cloth masks were also used by HCWs to protect from TB during the 1930s and 1940s (Wheeler 1938, Lurie and Abramson 1949, McNett 1949). During this period, facemasks had been also used by sick patients to prevent the spread of infection to others, also termed “source control” (Weaver 1919, Rockwood and O’Donoghue 1960, Jensen et al. 2005). Medical masks were developed in the midst of twentieth century (Kiser and Hitchcock 1958, Madsen and Madsen 1967) and since then largely replaced use of cloth masks except in low resource settings, where they are still widespread in use. Respirators are relative new products and their use is increasing rapidly particularly in high resource settings (OSHA 2016a).

16.2.1 Types of Facemask and Respirators

The following types of facemasks and respirators are commonly used in healthcare, community, and industrial settings (IOM 2006, OSHA 2014):

1. Facemasks
 - a. Medical or surgical masks (here after “medical masks”)
 - b. Cloth, cotton, or gauze masks, (here after “cloth masks”)
2. Respirators
 - a. Air purifying or particulate respirators
 - i. Disposable filtering facepiece respirators (FFRs)
 - ii. Reusable or elastomeric respirators
 - iii. Powered air-purifying respirators (PAPRs)
 - b. Air supplying or atmosphere-supplying respirators
 - i. Supplied-air respirator (SAR)
 - ii. Self-contained breathing apparatus (SCBA)

Air supplying or atmosphere-supplying respirators are generally not used in healthcare, and are reserved for chemical, smoke, or gas contamination, so will not be reviewed further. Characteristics of various types of facemasks and respirators used in healthcare are presented in [Table 16.1](#).

16.2.2 Facemasks (Medical and Cloth Masks)

16.2.2.1 Shape

Medical masks are generally available in two shapes: flat-pleated or duck-billed and premolded. Most medical masks are not able to be fitted to the face, and there is significant air leakage between the mask and the face. Flat-peaked or duck-billed-shaped medical masks are attached to the head with two ties. Premolded medical masks are attached to the head with a single elastic string (MacIntyre et al. 2011, 2014c). Some medical masks are adjusted to the bridge of the nose with a flexible metal piece. Cloth mask are generally flat-pleated and attached to the head with a single elastic string or two ties.

16.2.2.2 Material and Filtration Mechanism

Medical masks are made of a three ply structure of nonwoven material, usually polypropylene (IOM 2006, US FDA 2014), spun-bonded, melt-blown, or wet-laid (US FDA 2014). Cloth masks are made of one or two layers of cotton, gauze, or silk (Chughtai et al. 2013a). Cloth masks are mostly used in resource-limited settings (IOM 2006). Filtration of facemasks through the mask material is by mechanical impaction, however a significant amount of air can leak between the mask and face as well. The risk of infection has been shown to be higher in wearers of cloth masks, possibly because of moisture retention and low frequency of cleaning (MacIntyre et al. 2015).

16.2.2.3 Regulation

In the United States, the FDA oversees the process of premarket notification submissions of medical masks and reviews the testing data provided by manufacturers (so-called “510(k)” submissions) to approve for marketing. Mask manufacturing companies are required to provide a description of the product, including material used, specification and dimensions, style and design features (US FDA 2014). The European standard for the regulation of medical masks (EN 14683:2005) requires manufacturers to perform testing and “self-certify” the device for EC approval under the Medical Devices Directive (93/42/EEC) (3M 2014a). In Australia, medical masks are required to meet Australia Standard AS 4381 (Standards Australia Limited/Standards New Zealand 2002). In most developing countries, regulations do not require use of medical masks, and the use of cloth masks is not regulated in any part of the world (Chughtai et al. 2015a,b,c).

TABLE 16.1
Characteristics of Various Types of Facemasks and Respirators Used in Healthcare

	Medical Masks	Cloth Masks	Filtering Piece Respirators (e.g., N95)	Elastomeric Respirators	Powered Air-Purifying Respirators
Sizes	Usually one size	No standard size	Range of sizes in some models	Facepiece in three sizes: small, medium, and large	Facepiece in three sizes: small, medium and large
Disposable or reusable	Disposable	Disposable	Disposable	Reusable	Reusable
Intention to use	Source control by patient or HCW in OT Prevent from splashes of blood and body fluids	Source control by patient or HCW in OT Prevent from splashes of blood and body fluids	Respiratory protection	Respiratory protection	Respiratory protection, in high-risk situations
Type of filters/ cartridge used	No	No	Particulate (N, P, or R types)	Particulate (N, P, or R types), gas/vapor (organic vapor, acid gases, ammonia/methylamine, formaldehyde, multi-gas) or combination particulate and gas	Particulate, gas and vapor cartridges
Filtration mechanism	Mechanical impaction	Mechanical impaction	Impaction, interception, diffusion and electrostatic attraction	Impaction, interception, diffusion and electrostatic attraction	Impaction, interception, diffusion and electrostatic attraction

(Continued)

TABLE 16.1 (Continued)

Characteristics of Various Types of Facemasks and Respirators Used in Healthcare

	Medical Masks	Cloth Masks	Filtering Piece Respirators (e.g., N95)	Elastomeric Respirators	Powered Air-Purifying Respirators
Filtration capacity	Protect from large particles, that is, >100 microns	No data	Protect from small particles, that is, <100 microns	Protect from small particles, that is, <100 microns	Protect from small particles, that is, <100 microns
Facial fit	No	No	Yes	Yes	Yes
Fit testing	Not required	Not required	Required	Required	Required
Fit (user seal) check	Not required	Not required	Required	Required	Required
Trainings required to use	No	No	Yes	Yes	Yes
Regulations and certification	No	No	Yes	Yes	Yes
Test protocols	Particle filtration efficacy, bacterial filtration efficacy, fluid resistance, and flammability testing	No	Filtration efficacy Total inward leakage	Filtration efficacy Total inward leakage	Filtration efficacy Total inward leakage
Extended use	No data available	No data available	No data available	No data available	Yes, depending on battery
Reuse after decontamination	Not recommended	Can be used after washing with but not data available	Not recommended	Yes, according to manufacturer instructions	Yes, according to manufacturer instructions

(Continued)

TABLE 16.1 (Continued)
Characteristics of Various Types of Facemasks and Respirators Used in Healthcare

	Medical Masks	Cloth Masks	Filtering Piece Respirators (e.g., N95)	Elastomeric Respirators	Powered Air-Purifying Respirators
Protection against droplet infections	++	+	+++	+++	+++
Protection against airborne infections	-	-	+++	+++	+++
APF	No data	No data	10	Half mask—10 Full mask—50	1000
Easy to don/doff	+++++	+++++	+++++	+++	++
Comfort with prolonged use	+++	+++	++	++	+++++
Used with facial hair	Yes, as facial fit is required	Yes, as facial fit is not required	No	Yes, with full facepiece	Yes, with full facepiece
Weight	+	+	++	+++	+++++
Cost	+	+	++	+++	+++++
Availability	+++++	++++	+++	++	+

Sources: Powered Air-Purifying Respirator (PAPR) Concept Paper, CDC. Occupational Safety & Health Administration (OSHA). Department of Labor. This sign shows strength of variable, e.g. + low protection, +++ high protection; + cost is low and +++++ cost is high

16.2.2.4 Efficacy and Use

Facemasks are used for two main purposes (Siegel et al. 2007, IOM 2010, WHO 2014a):

- Source control (worn by HCWs in operating theatre environment or by sick patients to prevent transmitting infection to others)
- Respiratory protection (worn by a well person to protect against acquisition of some infections)

16.2.2.4.1 Facemask Use as Source Control in Operating Theatre Environment

Facemasks were originally developed to prevent spread of infections from the wearer, that is, from both patients and HCWs, referred to as “source control” (Belkin 1997). The traditional use of facemasks was in OTs to reduce the transfer of potentially infectious body fluids from the surgeon to sterile areas, however the effectiveness of facemasks in preventing surgical site infections is yet to be proven. Many historical studies have showed that facemasks do not prevent surgical site infections (Orr 1982, Mitchell and Hunt 1991, Tunevall 1991). Lipp and Edwards (2014) conducted a systematic review and reported low efficacy of facemasks against surgical site infections. The rate of surgical site infections was even higher in the masked group than the control group in some of these studies (Orr 1982, Mitchell and Hunt 1991, Tunevall 1991). Laslett and Sabin (1989) evaluated the use of medical masks and surgical caps in 504 patients undergoing percutaneous cardiac catheterization. They concluded that medical masks and surgical caps were not necessary to prevent infections during cardiac catheterization. In a hospital-based study, facemasks were not used during approximately 1000 surgical operations, and there was no increase in the infection rate compared to the infection rate in the previous 5 years in the same hospital (Orr 1982). Tunevall conducted a large clinical trial in 1991 and examined the rates of post-operative infections in patients operated on by “masked” and “unmasked” surgical teams. The rate of surgical site infection was 3.5% (73/1537) in the no mask group compared to 4.7% (55/1551) in the mask group. The authors concluded that the use of facemasks may protect the surgical team from acquiring infections but does not prevent surgical site infections. Experimental studies have also demonstrated that small amounts of oral bacteria dispersed during normal breathing may not contaminate the operating field and the use of facemasks may not be necessary in the OT subject to the availability of proper ventilation (Mitchell and Hunt 1991).

In contrast to this, there are other studies which support the use of facemasks in OTs. Chamberlain and Houang (1984) started a randomized control trial in women having gynecological surgery. The trial had to be discontinued in the initial phase because the rate of wound infection was found to be higher without mask use. Alwitry et al. (2002) attempted to measure the amount of bacteria that fell on the operative field during cataract surgery by

placing culture plates near the patients' heads. The amount of bacteria that fell on the operative field was significantly lower when the surgeon used a medical mask, compared to when the surgeon did not use a mask.

16.2.2.4.2 Facemask Use as Source Control by Sick Patients

Current evidence suggests that facemasks reduce the spread of infections from sick patients. Medical and cloth masks are commonly used to prevent spread of respiratory infections from the wearer (IOM 2010). In an experimental study, Johnson et al. (2009) reported that both medical masks and N95 respirators prevent the spread of the influenza virus from the wearer. Milton et al. (2013) collected samples of "fine" and "coarse" exhaled particles from 37 influenza cases before and after using medical masks. Wearing a medical mask was associated with 2.8-fold reduction in the shedding of "fine" viral aerosols and a 25-fold reduction in shedding of "coarse" viral aerosols (an overall 3.4-fold reduction, 95% CI 1.8–6.3). Dharmadhikari et al. (2012) checked the rate of infection in guinea pigs which breathed the air coming from the wards of multi drug resistant TB (MDR-TB) patients. The patients were grouped into "mask" and "no mask" groups and tuberculin skin test (TST) conversion rates were then observed among the guinea pigs. The rates of infection in guinea pigs when patients used and did not use masks were 40% and 76.6%, respectively, and the authors concluded that the risk of TB transmission might be reduced by 56% if patients used a mask.

Most clinical trials on facemasks have focused on the protection of the well wearer, rather than on source control (MacIntyre and Chugtai 2015). To date only two clinical trials have tested the use of medical masks worn for source control (on sick subjects to protect others from dissemination of infection from the source) in the community/household settings (Canini et al. 2010, MacIntyre et al. 2016). Canini et al. (2010) conducted a household trial to examine the role of facemasks as source control. The study could not find significant difference in two arms, however the trial was terminated early due to low recruitment and influenza A (H1N1)pdm2009 infection. Another study in China showed that medical masks may protect spread of respiratory infections from the wearer, however the study was small and underpowered to detect a significant difference in the intention to treat analysis (MacIntyre et al. 2016). There has been no clinical trial to examine the efficacy of masks as source control in a healthcare setting, yet mask use by sick patients is widely practiced globally. There is a need to conduct a large clinical trial in selected hospitals to examine the role of medical masks as source control.

The use of facemasks is particularly recommended by sick individuals in a hospital setting to prevent the spread of infection to other patients. HCWs may protect themselves through vaccination or use of PPE, but other patients may be vulnerable. Moreover, compliance with mask use may be higher in sick individuals compared to healthy HCWs. The use of facemasks by sick individuals is not only beneficial in healthcare settings, but may also help in reducing transmission in community settings,

particularly to household members and other close contacts (MacIntyre and Chughtai 2015).

16.2.2.4.3 Facemasks Use for Respiratory Protection

Despite the fact that facemasks have been used for the prevention of respiratory infections for a long time, their role in respiratory protection is much debated. Cloth and medical masks had been used in the past to protect from various respiratory infections (Capps 1918, Weaver 1918, Whitelaw 1919, Armstrong 1920, Wu 1926, Eh 1949, Chughtai et al. 2013a). Currently medical masks are commonly used in the healthcare and community settings, and use of cloth masks is limited to low-resource countries where they are a cheaper, reusable option compared to disposable medical masks. Three clinical trials compared the efficacy of medical masks compared to respirators (Loeb et al. 2009, MacIntyre et al. 2011, 2013). There is some evidence that medical masks may also protect HCWs from droplet transmitted infections, clinical respiratory illness (CRI), and influenza-like illness (ILI), though they are less effective than a respirator (Chen et al. 1994, Seto et al. 2003, MacIntyre et al. 2011, 2013). Medical masks had been used to protect HCWs from SARS, and many studies showed that they were effective in reducing transmission of infection in healthcare settings (Seto et al. 2003, Loeb et al. 2004, Teleman et al. 2004). One potential benefit of medical masks could be protection from a severe form of disease due to less viral load. A study in Taiwan during the SARS outbreak showed low viral load in nasopharyngeal swabs of HCWs (24.36 ± 15.84 copies/mL) compared to non-HCWs (4346 ± 3246 copies/mL). The authors concluded that that facemask use might reduce viral load in HCWs, resulting in low morbidity and mortality, less secondary transmission, and few long-term complications (Lu et al. 2006).

There is a lack of sufficient data to support the effectiveness of cloth masks in blocking the transmission of infections (IOM 2006). To date only one clinical trial has been conducted to test the efficacy of cloth masks which showed that cloth masks are less effective compared to medical masks and may actually increase the risk of infection (MacIntyre et al. 2015). Laboratory studies have demonstrated that cloth masks may provide some protection, but much less than a respirator or a medical mask (van der Sande et al. 2008, Davies et al. 2013).

The role of facemasks in community settings is yet to be proven definitively, and most studies are inconclusive. Seven clinical trials have been conducted in community or household settings (MacIntyre and Chughtai 2015), and most of them failed to show the efficacy of facemasks in intention to treat analysis. However post-hoc analyses showed a protective benefit, given that interventions were applied early and participants adhered to facemask use.

16.2.3 Respirators

Respirators are defined as “respiratory filtering devices that provide protection against inhalation of small and large airborne particles” (CDC 2006a).

According to OSHA (2011), a “respirator is a device that protects from inhaling dangerous substances, such as chemicals and infectious particles.” Respirators work through various mechanisms including filtering hazardous particles from the air, removing contaminants with chemicals, and supplying clean air from outside. Common types of respirators used in healthcare settings are air-purifying or particulate respirators and air-supplying or atmosphere-supplying respirators. Air-supplying respirators are used in very high-risk situations such as smoke exposure, chemical or gaseous exposures, where a separate air supply is required.

16.2.4 Air-Purifying Respirators

16.2.4.1 Types and Shape

Air-purifying respirators are further categorized into FFR or disposable respirators, elastomeric or reusable respirators, and PAPRs ([Figure 16.1](#)) (OSHA 2011). FFRs come in various shapes, for example, cup, duckbill, and molded. Reusable or elastomeric respirators are either full face or half face. Elastomeric respirators and PAPRs are reusable. Elastomeric respirators are either half or full masks.

PAPR is “a device equipped with a facepiece, hood or helmet, breathing tube, canister, cartridge, filter, canister with filter or cartridge with filter and a powered blower” (CDC 2008). It is of two types: tight fitting, with a seal to the face and neck (like a mask) and loose fitting (such as a hood), which may not completely seal the face and neck. PAPRs are also described as “respirators that protect the user by filtering out contaminants in the air and use a battery-operated blower to provide the user with clean air through a tight-fitting respirator, a loose-fitting hood, or a helmet” (IOM 2015). The components of a PAPR include a facepiece or hood/helmet, a breathing tube, a canister or cartridge with filter, a blower and a battery pack. Widely used negative pressure respirators (filtering facepiece and elastomeric) have significant disadvantages including high breathing resistance, acceleration of heat build-up, and CO₂ and moisture accumulation in the mask (OSHA 2008). This makes them difficult to tolerate over long periods of wear and can result in impaired professional performance, dizziness, and low compliance, which in turn increases the risk of non-compliance (Radonovich et al. 2009, MacIntyre et al. 2011, Kuklane et al. 2015). HCWs prefer respirators that are comfortable, keep them cool, and do not interfere with breathing (Baig et al. 2010). PAPRs are positive pressure devices because they use a blower to draw air through a filter into the facepiece. The airflow feels cool and refreshing. The protection of a PAPR is consistently higher than negative pressure respirators. Due to the positive airflow removing CO₂ and moisture, PAPRs are easier to wear over long periods of time. Despite these important advantages PAPRs are rarely used in healthcare.



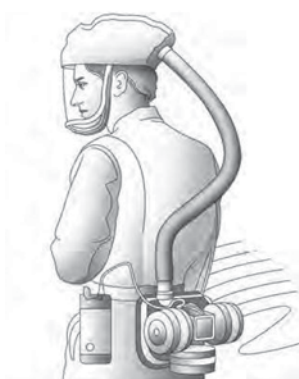
Filtering facepiece respirator



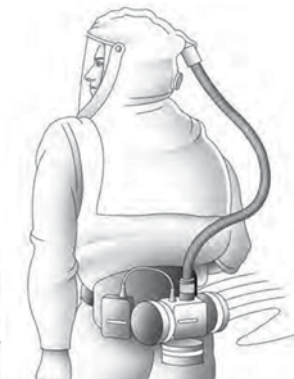
Half mask (elastomeric)



Full facepiece (elastomeric)



Loose-fitting powered air-purifying respirator (PAPR)



Hood powered air-purifying respirator (PAPR)

FIGURE 16.1

Respirator types. (Courtesy of Occupational Safety & Health Administration, U.S. Department of Labor Assigned Protection Factors for the Revised Respiratory Protection Standard. <https://www.osha.gov/Publications/3352-APF-respirators.pdf>.)

16.2.4.2 Material and Filtration Mechanism

FFRs are completely made of the filter material and are single use. The filters are typically made of polypropylene wool felt or fiberglass paper (NIOSH 1987, OSHA 2009b, 2011). The facepiece of elastomeric respirators is either of full face or half face, and made of rubber, neoprene, silicone, or plastic. Silicone is usually preferred because it is comfortable, flexible, and easy to wash. The facepiece of the elastomeric respirators may be cleaned and reused, however its cartridge is discarded and replaced.

FFRs and elastomeric respirators are non-powered. Instead, the wearer draws air in through the filter or cartridge, creating negative pressure inside the respirator. Some respirators also have an exhalation valve so that negative pressure is not created inside. Breathing is improved as valves are opened during the exhalation. However, respirators with exhalation valves should not be used when there is a chance of spreading an infection from the wearer (OSHA 2009b, 2011). PAPRs have a battery system, which is used to pull contaminated air through the filter piece. They use a high-efficiency particulate arrestance (HEPA) filter to protect the wearer against airborne infections and are used during aerosol-generating procedures (AGPs) such as intubation, suctioning, and bronchoscopy. Fit testing is not required for full-facepiece PAPRs and they can be used by men with facial hair, however half mask PAPRs need to be fit tested (OSHA 2009b, 2011). PAPRs are much more comfortable than FFRs and can generally be tolerated much longer. Battery time is generally long with warning indicators in case of low battery. However, PAPRs must be cleaned when used to protect against pathogens that can be spread by contact, and batteries need to be replaced. The required belt, hose, and battery pack may also become contaminated.

Three types of filters are used in cartridges of reusable respirators: particulate filters, gas/vapor filters, and combination filters (3M 2014b). Particulate filters are mostly used in healthcare settings and they only filter aerosols such as dust, mists, fumes, smoke, mold, and bacteria. Gas and vapor filters are mostly used in industrial settings and are different for organic vapor, acid gas, ammonia/methylamine, and formaldehyde. Combination filters protect from both particles and gases (3M 2014b).

The filtration process for particulate filters is different for large and small particles. Large particles do not pass through the filter media and collide with the respirator fiber and may be captured by interception, sedimentation, and inertial impaction. Small particles may pass the fiber filter through diffusion. As particle size decreases, the diffusive capacity of particles increases due to temperature. Electrostatic capture of the charged particles is another filtration mechanism, which facilitates interception and diffusion as well. Chemical decontamination is the method used by gas mask respirators (OSHA 2009b, 2011).

Air-purifying respirators are classified into three filter series (N, R, and P) depending on their ability to resist oil. The “N” means not resistant to oil, the

“R” means somewhat resistant to oil, and the “P” means strongly resistant to oil (i.e., oil proof) (OSHA 2011). Three filtration efficiency levels (i.e., 95%, 99%, and 99.97%) exist for N, R, and P series, thus making a total of nine different types. “N” series respirators are tested with sodium chloride aerosols, while “R” and “P” series are tested with oil based aerosols. The assigned protection factor (APF) is calculated by estimating the ratio of the number of particles outside the respirator to the number of particles inside the respirator (Table 16.2) (OSHA 2009b, 2011). Selection of the respirator depends on the nature of organisms, transmission mode, dissemination method, concentration of aerosols, and other environmental conditions (CDC, 2001).

16.2.4.3 Efficacy and Use

To date, only FFRs (N95) have been tested in the clinical setting. Among five clinical trials in healthcare settings, three compared the efficacy of masks with respirators. Two large clinical trials clearly showed the benefit of using respirators for CRI (MacIntyre et al. 2011, 2013). However, none of the studies showed the efficacy of respirators against laboratory-confirmed influenza, probably due to inadequate statistical power. Seven clinical trials have been conducted in community or household settings (MacIntyre and Chughtai 2015), and all except one (MacIntyre et al. 2009) examined the efficacy of only facemasks. Only one clinical trial in a household setting compared the

TABLE 16.2

Assigned Protection Factors for Commonly Used Respirators^a

Type	Assigned Protection Factors	Remarks
Half-mask (FFR) (e.g., N95)	10	Needs to be fit tested
Half-mask (Elastomeric)	10	Needs to be fit tested
Full facepiece (Elastomeric)	50	Needs to be fit tested
Half-mask PAPR	50	Needs to be fit tested
Full-facepiece PAPR	1000	With Workplace Protection Factor ^b
Loose-fitting PAPR	25	No fit testing
Helmet/Hood PAPR	1000 ^a	If Workplace Protection Factor ^b not performed then 25
Full facepiece SAR	1000	APF = 10,000 (if used in “escape” mode) Needs to be fit tested
Full Facepiece SCBA, Pressure demand or other positive-pressure mode	10,000	Needs to be fit tested

^a Adapted from Occupational Safety & Health Administration (OSHA). Assigned Protection Factors for the Revised Respiratory Protection Standard. 2009a. <https://www.osha.gov/Publications/3352-APF-respirators.pdf>. (Accessed Nov 16, 2016)

^b Study that estimates the protection provided by a respirator within a specific respirator program.

efficacy of medical masks and respirators and found rates of ILI were similar (MacIntyre et al. 2009).

Respirators are used to protect from inhaled droplet or aerosol particles, including infection, dust, smoke, gases, vapors, and sprays. Properly fitted respirators are designed to fit tightly to the face and have been found to provide better protection against airborne and droplet infections compared to medical masks (Checci et al. 2005, van der Sande et al. 2008, Gralton and McLaws 2010, MacIntyre et al. 2011, 2013). FFR are commonly recommended for airborne infections (e.g., TB) (Nicas 1995, Jensen et al. 2005, WHO 2009) and high-risk procedures (e.g., AGPs) in healthcare settings (Chughtai et al. 2013b, WHO 2014a). However, FFRs do not provide protection against vapor and gases. They also provide little protection against direct liquid splash/spray of blood and body fluids, and surgical N95 respirators are recommended for this.

Some studies have suggested that respirators should also be used to protect from exposure to “surgical smoke,” which is an aerosol generated in surgery due to a laser or diathermy (Bruske-Hohlfeld et al. 2008, Ulmer 2008). The use of fit tested respirators is recommended in OTs to prevent inhalation of infective material from the surgical site which may include certain micro-organisms and may be harmful to the surgical team (Benson et al. 2013). Researchers argue that the use of surgical masks may only prevent exposure to splashes of blood/body fluids during the operation, and OT staff should use a respirator to protect themselves from infective aerosols generated by modern surgical technologies (Benson et al. 2013).

FFRs are, however, difficult to wear for long periods of time due to increased heat, moisture, and CO₂ in the facepiece. FFRs with exhalation valves are significantly more comfortable, as the exhaled air is directed through a valve that also mitigates increases in temperature, relative humidity, and CO₂. There is some concern in healthcare settings that the exhalation valve may allow the release of infectious particles generated by the wearer, although there are no data to support or refute this (IOM 2006). Another type of respirator is the surgical respirator which offers the combined protective properties of both a FFR and facemask (OSHA 2008). They protect from respiratory infections as well as from splash and spray of blood and body fluids.

Elastomeric respirators and PAPRs are increasingly being used in the healthcare setting. Although there is no efficacy data to support their use, simulated studies have shown that they offer better protection compared to the disposable N95 respirator (Lawrence et al. 2006). The CDC also recommends the use of PAPRs when performing high-risk procedures on TB and Ebola patients (Jensen et al. 2005, CDC 2014c). PAPRs were also recommended and used during the SARS outbreak in Canada (Wong 2003). There are some important disadvantages of PAPRs, however. The blower can be noisy and annoying, interfere with communication, and requires batteries (generally a battery pack on the back, worn on a belt with a hose) that need regular charging (OSHA 2008). While some pieces can be disposable (e.g., hoods), most

parts of a PAPR are not and require cleaning and disinfection between uses. Some of these parts (e.g., hoses, belts, and battery packs) are not easy to clean and disinfect; disposable covers may be required to prevent their contamination. PAPRs are more expensive to purchase and maintain, although the long-term costs can be less than disposable FFR if frequent use is required. When the blower and batteries are worn on a belt, they can interfere with healthcare tasks. Donning and doffing are more complex for a PAPR than a disposable FFR, but the chance of infection during doffing may be reduced because there is less chance for direct skin contact with contaminated hands or gloves (Zamora et al. 2006).

16.2.5 Policies and Practices on Use of Facemask and Respirators in Various Settings

There is an ongoing debate around the efficacy of various types of facemasks and respirators in healthcare settings. Many facemask studies have been observational (case control, cross sectional, or case studies) or conducted in controlled laboratory settings, and only recently has there been evidence from randomized clinical trials (RCTs) (MacIntyre and Chughtai 2015). Health organizations and countries have varying policies and practices on selection and use of facemasks and respirators in healthcare settings (Chughtai et al. 2013b, MacIntyre et al. 2014c).

Chughtai et al. (2013b) reviewed policies around the use of facemasks and respirators and examined guidance documents of the WHO, the CDC, and selected high, middle, and low-income countries. A lack of consistency in policies and guidelines was observed. Various types of facemasks and respirators were recommended for influenza (seasonal and pandemic strains), SARS, and TB. The WHO and the CDC have the same policy for seasonal influenza and TB, but different ones for pandemics influenza and SARS. Similarly selected counties have different policies on selection of facemask and respirators, which were in line with the WHO or CDC. MacIntyre et al. (2014c) examined the guideline on the use of facemasks and respirators for Ebola virus disease (EVD) during the 2014 outbreak. Although most countries and health organizations recommended a respirator to protect from EVD, some recommended medical masks as well. Another inconsistency was varying recommendation for frontline HCWs and laboratory workers, with a lower level of protection recommended for frontline HCWs compared to lab workers for Ebola. Of all the guidelines of selected countries and health organizations, only two (UK and South Africa) have the same respiratory protection policy for HCWs and laboratory workers.

Due to conflicting policies and lack of clear guidance, HCWs have varying practices with the use of facemasks and respirators (Chughtai et al. 2015c). Some of these practices are not in line with national infection policy, are non-standardized, and are not evidence-based (Chughtai et al. 2015a,c). Current practices are also influenced by availability, resources, and risk perception.

During the Ebola epidemic of 2014, for example, the perception of risk and demand for respirators was high. Although the available evidence points to cloth masks increasing the risk of infection (MacIntyre et al. 2015), some health organizations recommend their use if respirators and medical masks are not available (IOM 2006). In a guidance document “Reusability of Facemasks during an Influenza Pandemic” by the Institute of Medicine (IOM) of the National Academy of Sciences, the members were hesitant to discourage the use of cloth masks despite acknowledging a lack of efficacy data at the time and the risk of infection to the wearer (IOM 2006). Similarly in a position paper, the Association for Professionals in Infection Control and Epidemiology (APIC 2009) in the United States also considered the use of cloth masks during pandemics in case of shortage of medical masks and respirators. In the infection control guidelines for “Viral Haemorrhagic Fevers in the African Health Care Setting,” both the WHO and CDC recommended using cloth masks if respirators or medical masks were not available (CDC and WHO 1998). It has been augured that cloth masks may be the only option for low-resource countries which may have no access to respirators or medical masks. However, the increased risk of infection shown in our RCT of cloth masks (MacIntyre et al. 2015) suggests that improved low-cost options are required.

In Western countries, facemask and respirators are not commonly recommended or used in community and household settings (MacIntyre and Chughtai 2015), though they are used in many Asian countries. However, their use is recommended in industrial settings to protect employees from various hazards. In the United States, Occupational Safety & Health Administration (OSHA 2015) has developed its Respiratory Protection Standard to protect from occupationally acquired infectious and noninfectious hazards. Employers are required to evaluate respiratory hazards and are mandated to implement a respiratory protection program in the workplace.

16.2.6 Selection of Appropriate Respiratory Protection

Although medical masks are commonly used to protect from respiratory infections, they are not designed to provide respiratory protection. Medical masks have consistently lower filtration efficiency compared to respirators which varies according to the material used (Chen et al. 1994, van der Sande 2008, Gralton and McLaws 2010). Even multiple medical masks worn at the same time were found to be less protective than respirators (Derrick and Gomersall 2005). Even high-filtration efficacy masks will not be protective unless there is a good seal to the face, and masks are not built to have a good facial seal. Laboratory studies have also demonstrated that medical masks have a lower filter efficiency (ranging from 10% to 90%) (Oberg and Brosseau 2008) and a lower capacity to remove sub-micrometer-size bio-aerosols (Chen and Willeke 1992, Weber et al. 1993, Rengasamy et al. 2009a). In some guidance documents, medical masks are not even included in the list of PPE (IOM 2010).

Respirators are designed for respiratory protection, and properly fitted respirators provide better protection compared to a medical mask. Respirators have different APF (Table 16.2), which is defined by OSHA (2009a) as, “the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program.” The protection factor is measured by calculating the ratio of the concentration of airborne particles outside the respirator (C_o) to the concentration inside the respirator (C_i).

Commonly used medical masks and respirators provide an adequate physical barrier though full-face respirators provide superior protection. Medical masks have varied degrees of filtration, while respirators generally have three filtration efficiency levels (i.e., 95%, 99%, and 99.97%). Medical masks are not fitted to the face, but respirators are designed to be fitted around the face which is ensured by fit testing and fit checking. None of the currently used medical masks and respirators have antimicrobial properties, but this remains a potential design feature to improve protection.

The selection of respiratory protection depends on many factors which may be broadly categorized into characteristics of the infectious agent, host/individual, and organizational factors (Table 16.3). A risk analysis approach should be used to select facemasks/respirators in healthcare and community settings (MacIntyre et al. 2014c).

16.2.6.1 Nature of the Infectious Agent

The election of facemasks and respirators in healthcare settings mainly depends on the type of infection and transmission mode (Table 16.4). Facemasks are generally recommended and used for infections believed to be transmitted by droplets, such as influenza and other common respiratory viruses. However, some organisms typically transmitted through droplet routes may also be transmitted through small particle aerosols. This mechanism is called opportunistic transmission (Roy and Milton 2004). For example, the primary modes of transmission of influenza are thought to be droplet and contact but it may also be transmitted through AGPs. Respiratory aerosols are generated during AGPs resulting in “aerosol transmission,” which may be different from classical “airborne transmission” in that although the pathogen is inhaled in the same way as in airborne transmission, transmission may occur only over short distances (Brosseau and Jones 2014). However, infectious aerosol particles can travel short and long distance depending on particle size, humidity, and other environmental conditions (Wang et al. 2005, Tang et al. 2006). “Airborne transmission” occurs over long distances (e.g., TB), whereas, “aerosol transmission” is a phenomenon which can occur in diseases transmitted more often through other routes but which may also be transmitted by respiratory aerosols under certain circumstances, such as during AGPs. N95 respirators or higher are recommended for both airborne and aerosol transmission. A pooled analysis of two large RCTs shows that

TABLE 16.3
 Facemask/Respirator Use for Selected Scenarios

Disease	Healthcare Setting		Community Setting	
	Low Risk ^a	High Risk ^b	Low Risk ^c	High Risk ^d
Seasonal influenza	1st choice: Medical mask ^{e,f} 2nd choice: Cloth masks ^g	1st choice: Respirator ^{e,f} 2nd choice: Medical mask ^g 3rd choice: Cloth masks ^g	Not recommended ^{e,f}	Not recommended ^{e,f}
Pandemic influenza	1st choice: Respirator ^e or medical masks ^f 2nd choice: Cloth masks ^g	1st choice: ^{e,f} Respirator, 2nd choice: Medical mask ^g 3rd choice: Cloth masks ^g	Not recommended ^{e,f}	1st choice: Medical mask ^{e,f} 2nd choice: Cloth masks ^g
MERS-CoV	1st choice: Respirator ^f or Medical mask ^f	1st choice: Respirator ^{e,f}	Not recommended	Not recommended
TB	1st choice: Respirator ^{e,f}	1st choice: Respirator ^{e,f}	Not recommended ^{e,f}	Not recommended ^{e,f}
Ebola virus	1st choice: Respirator ^e or Medical mask ^f 2nd choice: Cloth masks ^g	1st choice: Respirator ^{e,f} , 2nd choice: Medical mask ^g 3rd choice: Cloth masks ^g	Not Recommended ^f	1st choice: Medical mask ^f 2nd choice: Cloth masks ^g

^a Routine patient care, not within 1–2 meters of infective patient.
^b High-risk situations, for example, AGPs, new or drug resistant organism, immunocompromised and other people with certain preexisting medical conditions.
^c Home, non-crowded settings.
^d Crowded settings, for example, public transport, preexisting illness, pregnancy, old age people (e.g., pandemic influenza), people touch human remains or in contact with infected animals (e.g., Ebola).
^e Centres for Disease Control and Prevention (CDC).
^f World Health Organization (WHO).
^g Not stated explicitly: inference drawn from Institute of Medicine (IOM) guidelines and other policy documents prepared for low recourse settings (Cloth masks should be only used when no other options available).

N95 respirators provide superior protection for droplet transmitting infections as well (MacIntyre et al. 2013).

The separation of transmission into droplet versus airborne is however based on outdated studies. Most organisms can be transmitted through more than one mode, and the relative contribution of each mode is often difficult to quantify. In the event of a newly emerging pathogen, the transmission mode may be uncertain. Moreover, some infectious agents that transmit predominantly through droplet (e.g., SARS) or contact (e.g., Ebola virus) might require

TABLE 16.4

Primary Mode of Transmission for Respiratory Infections

Predominant Presumed Mode of Transmission	Examples of Virus	Examples of Bacteria
Droplet	Influenza A & B ^a , Coronavirus ^a	<i>Streptococcus pneumoniae</i> , <i>Haemophilus influenzae</i>
Airborne	Rhinovirus A and B	Tuberculosis, <i>Bordetella pertussis</i> ^a
Contact	Adenovirus, parainfluenza virus, respiratory syncytial virus, MERS-CoV ^a	

Source: MacIntyre CR, Chughtai AA. *British Medical Journal (Clinical Research ed)* 2015;350:1–12. Epub 2015/04/11

^a Primary droplet but air borne transmission may occur in high risk.

superior respiratory protection due to other secondary modes of transmission. If there is high morbidity, mortality, or uncertainty about transmission mode, the precautionary principle should be followed. N95 or higher quality respirators should be the preference during outbreaks and pandemics where there is uncertainty around the transmission mode of the pathogen, especially when the disease in question has a high case-fatality rate and when there are no proven pharmaceutical interventions (IOM 2010, Chughtai et al. 2013b, CDC 2014a, WHO 2014a, MacIntyre et al. 2014c). All these factors should be considered when considering transmission-based precautions.

If the risk of transmission through the eye and other exposed body parts is high, a respirator equipped with a full facepiece, helmet, or hood should be used (Bollinger 2004). Finally, there is a complex relationship between bacteria and viruses in the respiratory tract, and dual infections appear to be common in HCWs, with multi-modal transmission (MacIntyre et al. 2014d).

For other contaminant, such as industrial particles, vapors, and gases, the selection of respirators with filters appropriate to the hazard is recommended. Chemical cartridges are recommended if risk of exposure to gases and vapors is high (Bollinger 2004). In contrast to healthcare setting, where respirators with “N” series filters are commonly used, respirators with “P” or “R” series filters may be used in industrial settings where oil particles are present in the atmosphere. Air-supplying respirators should be used in very high-risk situations, such as immediately dangerous to life or health (IDLH), oxygen deficit environments, and in the event of a bioterror attack.

16.2.6.2 Individual Factors

Individual factors are important in selection of respiratory protection, particularly for respirators. FFR and half facemask elastomeric respirators are not suitable for people with facial hair. Medical evaluation is necessary for FFR use as they may cause significant breathing problems. People with heart and

respiratory diseases should not use FFR. Some people experience adverse events such as headache, skins reaction, and fatigue. Risk perception is also an important factor which may impact on compliance. A survey in the US revealed that HCWs were willing to work during a pandemic given their employer provided them respirators (Gershon et al. 2010).

16.2.6.3 Organizational Factors

Organizational factors are important because under Workplace Health and Safety (WHS) obligations, employers are responsible for providing a safe workplace for their employees. It is the responsibility of the employer to provide appropriate facemasks, respirators, and other PPE and adopt necessary administrative and environment control measures to minimize the exposure to hazardous substances at the workplace. At the organizational level, the permissible exposure limit (PEL) is calculated to estimate maximum use concentration (MUC). According to OSHA (2009a), "MUC means the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator, and is determined by the APF of the respirator or class of respirators and the exposure limit of the hazardous substance." Air sampling is done to estimate the exposure limit and select respirators with appropriate APF.

Availability of facemasks and respirators of appropriate type and different sizes is of the utmost importance. Other organizational factors include resources for procurement, training, and fit testing, organizational culture, compliance with infection control practices, and monitoring and surveillance.

16.3 Respiratory Protection Program

A respiratory protection program is developed for healthcare organizations to ensure proper use of respirators. There are six main components of a respiratory protection program: (1) regulations and certification; (2) medical evaluation and surveillance; (3) training; (4) fit testing and fit checking; (5) availability, storage, and maintenance; and (6) reuse and decontamination.

16.3.1 Regulations and Certification

Respirator use should be regulated by an authority, and only certified respirators should be used by HCWs. In the United States, NIOSH regulates the testing and certification of respiratory protection equipment (NIOSH 1987). NIOSH tests filters for the effects of loading particle burden, temperature, and relative humidity, and requires a minimum filtration efficiency of 95%, 99%, or 100%. Filters can be certified for a range of efficiency classes (e.g., 95%, 99%, or

100%) as well as for their ability to withstand degradation as a result of loading or oil mist exposures. N95 filters cannot allow more than 5% of the challenge aerosol concentration to penetrate the filter, and would be expected to have less aerosol penetration with either larger or smaller particles than the size used in certification testing (IOM 2006, 2010). In Europe, European Norm (EN) standards are followed for testing respirators. Respirators need to be marked with “Conformité Européen (CE),” which means that the respirator meets the criteria of EN certification (European Directive 1989). Various types of the filtering facepiece respirators used in Europe are: FFR1, FFR2, and FFR3, which meet minimum filtration efficiencies of 80%, 94%, and 99%, respectively (Rengasamy et al. 2009b). FFR1, FFR2, and FFR3 are equivalent to NIOSH-certified N95, N99, and N100 respirators. In Australia, AS/NZS 1716 standard regulates respirator use, and P2 is equivalent to the N95 respirator (3M 2009). Regulation and certification is not routinely performed in low-resource countries and due to this, respirators of different filtration efficacy are used (Chughtai et al. 2015a,c). While regulations for filtration occur in many countries, the adequacy of facial fit is unregulated and therefore varies widely between respirators.

16.3.2 Medical Evaluation and Surveillance

Medical evaluation is an important component of a respiratory protection program to ensure that wearer can tolerate the respirator. Frontline responders should be medically fit and should not have serious cardiac or respiratory problems. Medical evaluation includes history of current and past illnesses, general physical examination, examination for facial scars, beards, body shape, and obesity (ECRI 2002). Moreover, medical surveillance program should be initiated to ensure proper use of respiratory protection and to record adverse events.

16.3.3 Training

Training, fit testing, and fit checking are important components of respirator use. The putting on (donning) and removal (doffing) of PPE is a laborious, slow process during which the smallest error can lead to contamination and infection (Kuklane et al. 2015). Training should be provided on the correct donning and doffing of respirators. Doffing is particularly a high-risk procedure, and the sequence becomes critically important if wearing full PPE gear (McLaws et al. 2016). During the doffing process, pathogens can be transferred from the contaminated surface of PPE to hands and other exposed body parts (Casanova et al. 2008). The outer layer of PPE should be decontaminated before starting the doffing process (MSF 2014, CDC 2014c).

Decontamination areas should be set up where staff don and doff the PPE. Decontamination sequences currently used for hazardous material emergencies should be used as appropriate for the level of protection employed. After removing PPE, frontline workers should have a shower using soap and

water, and change into clean clothes (CDC 2001). For high-risk exposures, no item of clothing worn during patient care (including socks and underwear) should be taken home by the HCW.

16.3.4 Fit Testing and Fit Checking

Fit testing and fit checking are important as loosely or improperly fitted respirators do not provide adequate protection to the wearer. Respirators come in various sizes and designs to fit a range of face shapes and to prevent leakage around the respirator. Fit testing is important to ensure the efficacy of respirators and even certified respirators do not provide the optimal protection unless correctly fitted (Coffey et al. 1999, Lawrence et al. 2006). Fit checking or testing is not needed for PAPRs, and for this reason some hospitals prefer PAPRs.

Fit testing may be qualitative or quantitative. In the qualitative fit test, Bitrex™, saccharin, or irritant smoke is released into a chamber. If the wearer tastes or smells these agents, it indicates inadequate fit (OSHA 2016b). The qualitative test is used to check the leakage around the face, however it does not quantify the amount of leakage. Air sampling is performed from inside the respirator in quantitative testing and the amount of leakage is calculated though a fit testing instrument such as a Portacount (OSHA 2016b). Fit checking (or user seal check) is different from fit testing and is necessary to ensure that respirators fit the face and are properly sealed (Danyluk et al. 2011). Fit checking should be done every time a HCW dons an N95 respirator, and both positive and negative pressure should be checked. Negative pressure testing is done through covering the filtration surface of respirator with the hands and inhaling inward to create negative pressure. A properly fitted respirator will move slightly inward if correctly fitted, while in case of a leak, it will not. In a positive pressure check, the wearer exhales outward, and a bulge on the outer surface shows proper fitting.

Studies show that hospitals may not comply with fit testing requirements and HCWs generally do not comply with fit checking procedures. A California study undertaken during the influenza A (H1N1)pdm09 showed that HCWs performed a fit check after donning a respirator only in 20% (3/15) of observations (Beckman et al. 2013). A survey of the members of the Society for Healthcare Epidemiology of America (SHEA) showed that less than one third of hospitals fit tested their employees before the start of the influenza A (H1N1)pdm09 pandemic (Lautenbach et al. 2010). Lastly, another study showed that approximately one third of the HCWs infected with influenza A (H1N1)pdm09 in the United States were never fit tested (Wise et al. 2011). However, very limited data is available from low and middle income countries.

16.3.5 Availability, Storage, and Maintenance

Stockpiling of respirators and other PPE is important to provide equipment to all frontline staff and to maintain supplies. The CDC has stockpiled a large

amount of medical supplies and PPE in case of emergency situations such as a terrorist attack, pandemic, or natural disaster (CDC 2015a). Supplies would be most needed in large metropolitan areas where most of the population lives. The CDC has developed a program, “Cities Readiness Initiative,” to quickly distribute medical and other supplies to 72 major cities where more than 57% of the US population resides (CDC 2015b). This is an example of deployment prioritization for the medical stockpile.

16.3.6 Reuse and Decontamination

Decontamination of used respirators is necessary to avoid the spread of infection and risk of self-infection to the wearer. Currently, very few data are available about decontamination of various respirators. The National Academy of Sciences has proposed that decontamination methods must meet the following criteria (IOM 2006):

1. The method must remove the infectious threat
2. The method must be harmless to the user
3. The method must not compromise the integrity of the various elements of the PPE.

Decontamination of medical masks and disposable filtering piece respirators is usually not feasible because the materials of these products degrade with standard means of disinfection. Various decontamination methods have been studied to date, including autoclave, isopropyl alcohol, bleach, hydrogen peroxide, microwave, soap and water, ultraviolet radiation, and dry heat (IOM 2006). The reuse of N95 respirators has been studied by Viscusi et al. in various studies (Viscusi et al. 2007, 2009). In the first study (2007), they tested 10 chemical and nonchemical decontamination methods. Among those, hydrogen peroxide and UV germicidal irradiation (UVGI) caused the least changes in the filtration performance. In the second study (2009), they tested five methods for decontamination of N95 filtering facepiece respirators: UVGI, ethylene oxide, vaporized hydrogen peroxide, microwave oven irradiation, and bleach. UVGI, ethylene oxide, and vaporized hydrogen peroxide were proven to be more effective methods than others. None of the three methods caused much physical change in the respirators. However, the throughput capabilities of ethylene oxide and vaporized hydrogen peroxide were not confirmed. Similarly, Lore et al. (2012) tested UVGI, microwave-generated steam (MGS), and moist heat (MH) for decontamination of the FFRs and found these methods effective in reducing viral load.

Respirators with a separate filtering piece (elastomeric respirators) are reusable, however the facepiece needs to be cleaned and the cartridge replaced. Disposable or elastomeric respirators may be useful in the event of high demand during pandemics (IOM 2006, 2010). OSHA (2009b)

recommends that NIOSH-certified elastomeric respirators can be used in situations when the reuse of respirators is required. OSHA has provided guidelines for cleaning and disinfection of respirators, which include disassembling (i.e., removing of filters, cartridges, or canisters), cleaning with warm water, and disinfection with detergent or disinfectant approved by the respirator manufacturer, rinsing and drying, and reassembling. Filters, cartridges, and canisters are replaced or repaired where necessary. Finally the respirator needs to be tested to ensure that all components work properly (OSHA 2014). The National Academy of Sciences has proposed that decontamination methods must meet the following criteria: (1) the method must remove the viral threat, (2) be harmless to the user, and (3) not compromise the integrity of the various elements of the respirator (IOM 2006). PAPRs should also be cleaned and disinfected after use. The instructions of the respirator manufacturer should be followed so that the agent used for the decontamination does not damage the respirator (Rengasamy et al. 2004).

Further research is required to test the effectiveness of various decontamination methods and to develop better materials which are resistant to degradation. Mask manufacturers generally recommend the single use of medical masks and filtering piece respirators and may not have a commercial interest in testing the reusability of masks and respirators due to financial and legal implications (IOM 2006).

16.4 Compliance

16.4.1 Compliance with Facemasks and Respirators

Regular and continuous use of facemasks and respirators is essential to provide maximum respiratory protection. Low compliance might result in acquiring infection regardless of how effective a respiratory protective device is. Compliance with the use of facemasks and respirators is reported to be low among HCWs and the general public and also dependent on various individual and environmental factors. Moreover, compliance decreases over the time due to overexertion and the presence of adverse events associated with mask use (Chughtai et al. 2016).

HCWs are reported to have low compliance with the use various PPE (Gershon et al. 1995, Evanoff et al. 1999). Wearing a facemask is considered “the most bothersome” (Nickell et al. 2004), and compliance with the use of facial protective devices is reported to be the lowest compared to other PPE (Madan et al. 2001, 2002, Chan et al. 2002). A systematic review suggests that compliance with the use of facemasks ranges from 4% to 55% (mean

30%) (Gammon et al. 2008). Self-reported compliance rates have been presented among clinical trials in HCWs. Compliance rates for cloth masks was reported to be 56% and for medical masks ranged from 66% to 84% (Jacobs et al. 2009, MacIntyre et al. 2011). Compliance with respirators varied according to the use and fit testing: 74% in fit-tested N95 respirators, 68% in nonfit-tested N95 respirators, 82% in targeted (in high-risk procedures only) N95 respirator use, and 57% in continuous N95 respirator use (MacIntyre et al. 2011, 2013).

Community and household studies also reported low compliance with facemasks and respirators among the general public. In some of these studies, both index (sick) cases and household members used a facemask, while in others, only household members used a facemask (MacIntyre and Chughtai 2015). Compliance with the use of facemasks was ranged from 45% to 52% in index cases and 21% to 68% in household members. Many individual and environmental factors also affect compliance with the use of facemasks and respirators (Chughtai et al. 2016).

16.4.2 Individual Factors

The use of facemasks is reported to be high in Asian cultures, such as in China and Japan (MacIntyre et al. 2011, 2013), but low in Western cultures (Ofner-Agostini et al. 2006, Seale et al. 2009). Among the individual factors, risk perception and the presence of adverse events are important predictors of compliance (Chughtai et al. 2016). Many studies show that adoption of certain behavior depends on the perceived risk. If the risk perception is higher, there is an increased probability of adopting protective behavior and vice versa. The Ebola outbreak in West Africa is an example when facemasks were recommended initially in the United States and recommendations were later changed following the infection of HCWs and concern about the high case fatality (MacIntyre et al. 2014b,c).

The presence of adverse events increases the risk of noncompliance with respiratory protection. Common adverse events associated with masks include general discomfort, pressure on nose, headache, breathing problems, and skin reaction (MacIntyre et al. 2011). In situations where high levels of PPE (full protective gowns and respirators) are required, such as for Ebola and other high-risk infections, duration of wear become important issues. During the 2014 Ebola epidemic, HCWs complained of unbearable heat, humidity, and discomfort when wearing PPE for periods longer than 30 minutes (Wolz 2014) resulting in HCWs removing PPE prematurely thus escalating disposable PPE costs and reducing HCW productivity and occupational risk.

A study testing the tolerance of respirators among US health workers found the discomfort increased with time if respirators were used continuously over prolonged periods of 8 hours (Shenal et al. 2012). However, most

of these symptoms may be subjective, as no significant physiological effects (measured as changes to transcutaneous carbon dioxide and oxygen saturation) were observed with long-term respirator use among intensive care unit nurses in a study in the United States (Rebmann and Wagner 2009). Negative pressure respirators (e.g., FFRs) are difficult to tolerate for a long time and result in more discomfort, dehydration (especially in hot climates), impaired professional performance, and lower compliance, which in turn increases the risk of infection (Radonovich et al. 2009, MacIntyre et al. 2011, Kuklane et al. 2015). In addition, more layers of the currently used PPE make it impractical to care for patients and increase the risk of injury or self-contamination. HCWs prefer respirators that are comfortable, disposable, keep them cool, and do not interfere with breathing (Baig et al. 2010). For Ebola, for instance, given the serious shortage of HCWs in affected countries and high infection rates (Liese and Dussault 2004), PPE that enables HCWs to work more comfortably for longer time periods, without compromising safety, is an urgent research need.

16.4.3 Organizational Factors

Organizational factors include resources, availability of facemasks and respirators, supportive organizational culture, and availability of fit testing and monitoring (Shigayeva et al. 2007, Nichol et al. 2013). The main problem with the use of respirators is the direct cost of the products and the indirect cost of implementing comprehensive respiratory protection programs including training and fit testing. However, cost should not be a factor while selecting appropriate respiratory protection for HCWs, and best practice guidelines should be evidence-based. To maintain the functionality and capacity of the healthcare workforce during outbreaks or pandemics of emerging infections, HCWs need to be protected. Under the WHS obligations, employers are responsible to provide a safe workplace for their employees. There are very few cost-effective studies to compare the cost of medical masks and respirators and disposable versus reusable respirators.

The availability of PPE is also important to ensure use and is also a predictor of compliance (Nelsing et al. 1997, Gammon et al. 2008). Shortage of facemasks and respirators was observed in many countries during influenza (H1N1)pdm2009.

Supportive organizational culture is important as well. In some settings, mask use was mandated in hospitals for unvaccinated HCWs to improve influenza vaccine uptake (Caplan and Shah 2013, Stuart et al. 2014). There is also new evidence that in the healthcare setting, if most HCWs are compliant with the use of a respirator, they may protect other noncompliant users as well due to herd protection effects (Chen et al. 2016). This study also showed that at least 50% adherence with the use of N95 respirator is required to protect from clinical respiratory infections.

16.5 Use of Facemask and Respirators in Special Situations

16.5.1 Facemask and Respirator Use in Outbreaks and Pandemics

Infectious diseases are a continuing threat with constant emergence or re-emergence of serious diseases in various parts of the world. Diseases originating from one region may spread rapidly to other regions due to human movement through travel, tourism, and trade, resulting in epidemics and pandemics. Epidemics of a new infectious disease may be devastating due to rapid global spread, high disease morbidity and mortality, and severe social and economic impacts. Rapid response is therefore required to control epidemics of emerging infectious diseases and to prevent morbidity and mortality. In the initial period of an outbreak, the characteristics of the pathogen may not be known, and a vaccine against the pathogen might not be available for many months or longer. Depending on the pathogen, drugs may or may not be available, and if available may not be available for everyone. Therefore, non-pharmaceutical measures, such as isolation, quarantine, social distancing, and PPE, are required for frontline response in epidemic situations (Bell et al. 2006, WHO 2014a).

Although facemasks, respirators, and other PPE are generally considered as the last line of defense in the infection control hierarchy (IOM 2006), they may be the only available option in event of a large scale outbreak or pandemic. Facemasks and respirators were widely used in healthcare settings during SARS, influenza (H1N1)pdm, MERS coronavirus, and other outbreaks. Most studies showed their benefit in reducing transmission of infection and protection of HCWs (Seto et al. 2003, Loeb et al. 2004, Teleman et al. 2004). Economic studies show that the use of facemasks and respirators are cost-effective in high-risk settings particularly when transmission and mortality rates are higher (Lee et al. 2011, Mukerji et al. 2017). However, the efficacy of using facemasks in a community setting is yet to be proven, and most observational studies showed limited benefit of using facemasks in mass gathering situations (Barasheed et al. 2016).

16.5.1.1 Selection of Facemasks/Respirators for Outbreaks and Pandemics

Currently there are limited data on the efficacy of various types of facemasks and respirators during outbreaks and pandemics. All RCTs in healthcare and community settings measured CRI, ILI, and/or influenza, and the results may not be generalizable to other infectious diseases (MacIntyre and Chughtai 2015). Most clinical trials are conducted during normal influenza seasons, but the pathogenicity and transmissibility of a pandemic strain might be different. Two RCTs were conducted during the influenza A (H1N1)pdm2009, and both were terminated early (Loeb et al. 2009, Canini et al. 2010). In the first RCT, medical masks were being compared with the N95 respirators, and

due to influenza A (H1N1)pdm2, all HCWs were asked to use N95 respirators (Loeb et al. 2009). In the second RCT, medical masks were being used as source control, and the trial was suspended due to the emerging pandemic (Canini et al. 2010). Due to conflicting evidence and strong cultural beliefs about infection control, health organizations and countries have different policies on the use of facemasks/respirators for pandemic influenza, SARS, MERS-CoV, and Ebola (MacIntyre et al. 2014c, MacIntyre and Chughtai 2015, Chughtai et al. 2015b).

Different strategies can be used to select facemasks and respirators for an outbreak or pandemic. For example, OSHA recommends categorizing employees into very high, high, medium, or lower risk of occupational exposure in preparing for an influenza pandemic and stockpiling facemasks and respirators (OSHA 2008). In some cases, a reusable respirator may be selected to overcome the shortage of disposable respirators.

Medical masks may be used in the community setting if the risk of transmission is very high. Respirator use is generally not recommended, but one trial showed they may protect in the community (MacIntyre et al. 2009). However, supplies may not be available for everyone. As a last resort, home-made cotton/cloth masks may be used, although they have lower filtration efficacy and facial fit compared to the medical masks (Davies et al. 2013). In addition, research shows that cloth masks increase the risk of infection (MacIntyre et al. 2015).

16.5.1.2 Increased Use

The use of facemasks and respirators increases during outbreak and pandemic situations (Lee et al. 2011). The WHO estimates around 233 million outpatient visits, 5.2 million hospital admissions, and 7.4 million deaths will occur globally within a very short period in event of a new pandemic (WHO 2014c). The CDC (2006b) estimated that approximately 1.5 billion facemasks and 90 million respirators would be needed by the health sector and around 1.1 billion masks would be needed by the public for a 6 week pandemic influenza outbreak. A shortage of facemasks and respirators was observed in many countries during the influenza A (H1N1)pdm2009 outbreaks (Rebman and Wagner 2009, Beckman et al. 2013). The supply of respirators was exhausted in many US hospitals, and HCWs had to reuse their respirators or had to rely on other types of facemask (Rebman and Wagner 2009, Beckman et al. 2013).

16.5.1.3 Nonstandardized Use and Risk of Infection

Due to increased use during outbreaks and pandemics, many nonstandard practices may be observed such as extended use and reuse of facemasks and respirators. According to the CDC (2010), extended use refers to “the practice of wearing the same N95 respirator for repeated close contact encounters

with several patients, without removing the respirator between patient encounters.” The CDC (2010) also defines reuse as “the practice of using the same N95 respirator for multiple encounters with patients but removing it (‘doffing’) after each encounter.” Currently data are lacking regarding the time period that the same mask or respirator may be continuously be used. Available data suggest that respirators may be used intermittently or continuously for around 8 hours (CDC 2014b), and adverse effects of facemasks increase with more than 8 hours of use (Shenal et al. 2012).

Disposable medical masks and respirators have a limited life span and can become deformed, damaged, saturated, or may become ineffective after a single use. In addition, constant use and moisture may lead to difficulty in breathing (IOM 2006). Single use of medical masks and FFRs is recommended, but this is not always feasible. During a pandemic or extended outbreak, medical masks and FFRs may not be available for everyone and reuse or extended use is needed in some situations. The reuse and extended use, however, may be associated with self-contamination given that the outer surface of medical masks or respirators may be soiled and could be a source of infection (Viscusi et al. 2009, IOM 2010). The number of viral particles and survival time are important factors to consider if reuse is deemed essential (IOM 2010). Research studies are required to test the safety and efficacy of reuse.

Health organizations and countries have developed some recommendations on the extended use and reuse of medical masks and respirators during outbreaks, pandemics, and other high demand situations (IOM 2006, OSHA 2009b, CDC 2010, CDC 2016). The CDC (2016) recommends extended use during SARS outbreaks provided the mask is not wet, soiled, or damaged. However, there are currently no clinical studies supporting this practice (Sonoma County Department of Health Services 2006, OSHA 2009b). Considering the high demand for respirators during pandemics, OSHA recommends the extended use of respirators if they are not soiled or damaged and are still functioning properly. Facemasks and respirators should be kept in a safe place, and the product should only be used by the same wearer (OSHA 2009b). During the SARS outbreaks, Health Canada (2003) advised medical masks and respirators could be reused if SARS was ruled out. In case of exposure to a confirmed SARS case, reuse of contaminated masks and respirators was discouraged. WHO advised HCWs to use respirators for an extended period for TB protection if the respirators are properly stored (WHO 1999). Extended use should be balanced against the risk of infection, and the wearer should not remove facemasks between patient encounters to avoid self-contamination (CDC 2010).

Another option is double masking, that is, using a facemask over a FFR to prevent soiling and to extend the life of a respirator (Roberge 2008). However, this may increase the breathing resistance (Sinkule et al. 2013). IOM (2006) has also recommended using facemasks over the respirators in a policy document on reusability of facemasks during an influenza pandemic. However,

there is limited data on the effectiveness of this strategy, and more research is needed.

During the SARS outbreak the CDC recommended concurrent use of facemasks with respirators in case of low supplies (CDC 2016). In a policy document, the IOM (2006) recommended using a facemask over the FFR to extend its life and prevent contamination on the outer surface. Double facemasks were also used during SARS outbreaks in Taiwan (Chen et al. 2004), however there is no clinical data to show the effectiveness of this intervention. The filtration effectiveness of multiple medical masks is reported to be lower compared to N95 respirators in a crossover trial of healthy volunteers (Derrick and Gomersall 2005).

16.5.1.4 Use in Community Settings during Outbreaks and Pandemics

Medical masks are recommended for the general public, although there is limited evidence around their effectiveness during outbreaks and pandemics. The RCTs conducted in community settings show that masks can protect people provided they are compliant, and provided the device is used early (MacIntyre and Chughtai 2015). During large outbreaks and pandemics, the focus may shift to delaying spread and reducing community transmission through population-based measures. Common interventions used to reduce the spread of epidemics in the community are quarantine and social distancing through closure of schools and workplaces and cancellation of nonessential public gatherings (Bell et al. 2006). However, the effectiveness of these interventions has not been quantified (Aledort et al. 2007), and there is an urgent need for research on the effectiveness of non-pharmaceutical public health interventions in the community.

16.5.2 Facemasks and Respirator Use for Biological Agents

Biological agents may be released accidentally (e.g., in a laboratory) or deliberately (e.g., bioterrorism). In laboratory settings, technicians and scientists generally use PPE according to a predetermined biosafety level, and risk of transmission is less in such a controlled environment. However, the nature of the pathogen, transmission mode, and its concentration in the air would be unknown in the initial stage of a biological attack. In the event of a covert attack, the symptoms may appear late (i.e., after the incubation period) and hospital and other frontline workers might not get a chance to use PPE. Moreover, secondary transmission might have already been started in case of highly infectious pathogens, such as modified strains of influenza and smallpox.

16.5.2.1 Selection of Respirators in a Bioterror Event

Biological agents are transmitted through various routes, making appropriate respiratory, skin, and eye protection required. The United States

Environmental Protection Agency (US EPA) has categorized PPE according to its level of protection (US EPA 2015). “Level A” is the highest level of protection and is used when maximum respiratory, skin, and eye protection is required. This includes SCBA, chemical and vapor protective suit, gloves, and boots. “Level B” protection includes SCBA and chemical resistant clothing, and is required when the highest level of respiratory protection and lesser skin protection is required. “Level C” and “level D” protections are lower levels of protection required for airborne and splash hazards, respectively (US EPA 2015).

The highest respiratory protection, such as SCBA or airline respirators (Figure 16.2), should be used if the biological agent is unknown, if an aerosol-generating device is used, and if the concentration of infective agent is very high in the air (CDC 2001, IOM 2006, OSHA 2009b, 2014). Air is supplied from an outer source in both types of equipment and the risk of inhalation is reduced significantly (ECRI 2002). SCBA supplies open- or closed-circuit air with positive pressure. In an open-circuit system, exhaled air is exhausted in the outer atmosphere, while in closed-circuit systems carbon dioxide is removed from the exhaled air and replaced with the oxygen. Air is supplied through a pump or a cylinder in case of airline respirators, and these products are suitable for work in small area such as isolation or decontamination room (ECRI 2002).

However, it may not be possible to select appropriate respiratory protection in case of sudden, covert, or unrecognized attack, which would be likely in case of bioterrorism. Many incidents have not been correctly recognized as bioterrorism in the past, so the detection of such events remains a challenge (MacIntyre 2015).

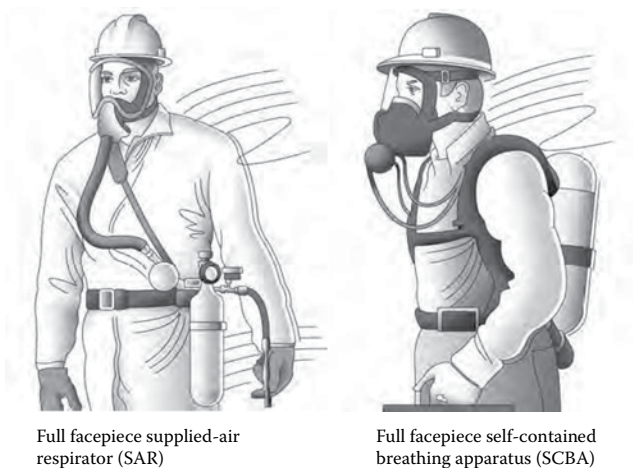


FIGURE 16.2

Supplied air and SCBA configurations. (Courtesy of Occupational Safety & Health Administration. U.S. Department of Labor Assigned Protection Factors for the Revised Respiratory Protection Standard. <https://www.osha.gov/Publications/3352-APF-respirators.pdf>.)

16.5.2.2 Training and Other Related Issues

Training should be provided on the correct use of air-supplying respirators which are not commonly used in healthcare and community settings. Incorrect use may harm the wearer as occurred in Israel during the Gulf war crisis when gas masks were provided to four million people (Hiss and Arensburg 1992). Despite the fact that instructions were provided to wearers, 13 people died of suffocation. Certain types of protective clothing are coated to provide protection against chemical hazards, so may cause heat stress. For this reason, a heat stress program is recommended for workers (ECRI 2002).

16.5.3 Industrial Products and Their Applications in Healthcare Settings

Many types of respirators are used in an industrial setting, and their applications in the healthcare setting have never been tested. PAPRs are more widely used in industrial applications, and there have been recent technological developments widely adopted in these markets which may have significant benefits for HCW protection. However, industrial PAPRs have not been tested in the clinical setting, and there is limited research on their practicality and comfort.

16.6 Case Studies

16.6.1 Case Study 1: Facemask and Respirator Use during Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) Outbreak in 2002–2003

SARS-CoV is a single-strand RNA virus (Peiris et al. 2003a, Ling et al. 2011, CDC 2014d) and is known to cause infection in both humans and animals (Peiris et al. 2003b). The virus first emerged from the Guangdong Province in Southern China in November 2002 (Breiman et al. 2003) and spread to 29 countries within a short time resulting in 8096 probable cases and 774 deaths (WHO 2014d). The virus mainly transmits through direct contact with mucus membranes and droplets (Ling and Seto 2011). There is some evidence of airborne transmission of SARS as well (Yu et al. 2004, Chen et al. 2009). Moreover, the risk of transmission is reported to be increased during AGPs, particularly tracheal intubation, noninvasive ventilation, and tracheotomy (Fowler et al. 2004, Tran et al. 2012). Among the total 8096 SARS cases, 1706 (21%) were HCWs. In some countries, the percentage of infected HCWs among total cases was extremely high. For example, out of a total of 63 SARS cases in Vietnam, 36 (57%) were HCWs. Similarly, the proportion of HCWs, among the total SARS cases, was also high in Canada (43%), Singapore (41%), Hong Kong (22%), Taiwan (20%), and China (19%) (WHO 2014d).

Facemasks and respirators were commonly used by HCWs and the general public during the SARS outbreak in 2002–2003. Most of the studies showed that both facemasks and respirators were protective against SARS (Seto et al. 2003, Loeb et al. 2004, Teleman et al. 2004). Facemask use in Vietnamese hospitals was associated with low SARS transmission (Nishiyama et al. 2008). Some researchers argued that the outbreak in Vietnam was contained without high-level infection control measures such as negative pressure rooms and N95 respirators, and medical masks were considered sufficient (Nicolle 2003). A case control study in five hospitals in Hong Kong supported the use of medical masks for SARS (Seto et al. 2003). Studies in Singapore (Teleman et al. 2004), Canada (Loeb et al. 2004), and Taiwan (Lu et al. 2006) also support use of either facemask or respirators to protect from SARS.

On the other hand, facemasks and respirators were found not to be protective against SARS in other studies (CDC 2003, Chen et al. 2004, Lau et al. 2004, Park et al. 2004). Interestingly, a study in the United States reported 110 HCWs exposed to SARS patients, of whom 45 (44%) did not use a medical mask or respirator. No case of SARS was reported in those 45 HCWs (Park et al. 2004). Of 73 HCWs exposed to initial SARS cases in Taiwan, around half did not use any mask/respirator and were not infected (Chen et al. 2004). A study in Hong Kong also failed to find a difference in the use of N95 respirators between SARS cases and controls. However, masks and respirators were found protective when combined with other PPE (Lau et al. 2004). Similarly, a low rate of infection was reported from a public hospital in Vietnam, despite the fact that N95s were unavailable in the initial period of outbreak and other control measures were applied (Le et al. 2004).

Health organizations and countries have different recommendations regarding selection and use of facemasks and respirators for SARS (Chughtai et al. 2013b). During the outbreak, the WHO (2007) recommended facemasks in low-risk situations and respirators in high-risk situations, whereas the CDC (2004) recommended respirators in both low- and high-risk situations. The guidelines of most countries were in line with the CDC, for example, the United Kingdom (Health Protection Agency UK 2005), Canada (Health Canada 2003), Australia (Department of Health and Ageing and the Communicable Disease Network of Australia 2004), Pakistan (Ministry of Health Pakistan 2006), and Vietnam (Ministry of Health 2003) also recommend respirators to protect against SARS. There was also an inconsistency in the selection of respirator. The CDC and most countries prefer N95 or equivalent respirators in low-risk situations with SARS patients, while the United Kingdom recommends an FFR3 (Chughtai et al. 2013a,b).

The last case of SARS was reported by the WHO on 5 July 2003. Although a few cases occurred later in 2003 and 2004, they were due to breaches in laboratory biosafety and sporadic community-acquired infection. Fortunately, significant secondary transmission did not occur (Department of Communicable Diseases Surveillance and Response 2004). Since 2004, no new cases of SARS-CoV have been reported anywhere in the world. However

in 2012, a novel coronavirus, Middle East respiratory syndrome coronavirus (MERS-CoV), emerged in the Middle East and spread to the United Kingdom and to a few other countries (Bermingham et al. 2012, Pollack et al. 2013). As of August 2017, more than 2000 laboratory-confirmed cases of MERS-CoV and 643 deaths have been reported to the WHO from 27 countries (WHO 2016a). There is the same controversy regarding the selection of respiratory protection for MERS. The WHO recommends medical masks for low risk and respirators for high risk (WHO 2016b), while the CDC recommends respirators in both situations (CDC 2015c). Most of the MERS cases were reported from Saudi Arabia and the Ministry of Health in Saudi Arabia also recommended respirators to protect from MERS (Scientific Advisory Council 2014).

16.6.2 Case Study 2: Facemask and Respirator Use during the Ebola Outbreak

Ebola is a filovirus and causes hemorrhagic fever in humans (WHO 2014e). Ebola was first reported in 1976 in the Democratic Republic of Congo, and since then sporadic cases and small-scale outbreaks have occurred in many central African countries (WHO 2015a). There are several strains of Ebola virus, but the Zaire strain commonly occurs in Africa and West Africa and can have a 90% case fatality rate (range 25%–90%). Fruit bats are considered as the natural reservoir and the disease transmits to humans through direct contact with other primates including monkeys, gorillas, and chimpanzees (Leroy et al. 2005). Human-to-human transmission of Ebola occurs predominantly through direct contact with blood and body secretions (Alimonti et al. 2014, WHO 2014e). There is some evidence of airborne transmission of Ebola as well (Dalgard et al. 1992, Johnson et al. 1995, Jaax et al. 1995, CNN 2014, Public Health Agency of Canada 2014).

Many issues were highlighted regarding the selection and use of PPE during the 2014 Ebola outbreaks in West Africa (MacIntyre et al. 2014a,b,c). As the predominant transmission mode of the Ebola virus is direct contact with blood and body fluids, the WHO, the CDC, and most countries initially recommended a medical mask with face shield to protect from Ebola (WHO 2008, CDC 2014e, MacIntyre et al. 2014b). These guidelines were challenged by researchers citing the high rate of infections among HCWs, low infective dose, high case fatality, and inconsistent recommendations for frontline workers and laboratory scientists (MacIntyre et al. 2014c). During the 2014 West African epidemic, the death toll for HCWs was high, with 1 in 10 (over 880) HCWs contracting Ebola. The case fatality rate was very high (around 90%) and infectious dose was very low. Initially, medical masks were recommended for frontline HCWs in unstable, contaminated, and unpredictable clinical environments, while respirators were recommended for the laboratory scientists who worked in highly controlled, sterile environments (Department of Health and Ageing Australia 2007, CDC 2014f).

The recommendations were subsequently changed by the CDC (but not the WHO) in favor of respirators and full body suits (MacIntyre et al. 2014b). Since then, the CDC and WHO have confirmed that PPE is an essential part of ensuring the occupational health and safety of HCWs caring for Ebola patients (MacIntyre et al. 2014b, WHO 2015b), and there has been a renewed focus on ensuring appropriate equipment and practices are in place.

The recent Ebola epidemic illustrated how vulnerable HCWs, and indeed the global community, are to infectious agents when healthcare policies are not well informed and updated (MacIntyre et al. 2014c).

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